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Companywide	Program Requirements Document	For Additional Info: http://EDMS	Effective Date: 07/30/04
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Manual: 13A Quality and Requirements Management Program Documents

Change Number: 111857

1. PURPOSE

This Program Requirements Document (PRD) provides quality requirements to support meeting the customer's needs and expectations for the type of research and development being performed. The purpose is to perform research that produces results that are respected and defensible within the scientific community.

2. APPLICABILITY

This PRD applies to R&D activities. The term *research and development* (R&D; see def.) includes two types of activities. The first type is scientific (i.e., work that results in the advancement of knowledge or development of technology). The second type of activity is secondary in nature and supports R&D science (e.g., procurement, maintenance, and operation of facilities). The application of specific *quality assurance* (QA; see def.) requirements shall be prescribed in the Quality Assurance Program Requirements Documents (QA PRDs), a *quality program plan* (QPP; see def.), or documented in a *project execution plan* (PEP; see def.). Implementation will be documented in written policies, procedures, or *laboratory notebooks* (see def.). Applying the specific QA requirements will be based on a *graded approach* (see def.).

R&D processes consist of three basic phases: basic research, applied research and developmental work. The quality assurance criteria specific to each phase is dependent on the complexity of the phase. See Appendix A for the QA requirements and when they are applicable to each phase.

Research and developmental activities with non-INEEL customers that have supplied documented quality requirements will be supported by allowing the use of those quality requirements in place of requirements defined in this PRD. Where customer quality requirements are not documented, this PRD is applicable.

This PRD does not apply to development work that has transitioned into design or production of engineered *items*. The QA PRDs (QA PRD-5070 through PRD-5092) control these activities. Appendix B provides the requirements basis.

2.1 Basic Research

Basic research (see def.) is conducted to acquire and disseminate new knowledge of a theoretical or experimental nature. Basic research has a number of specific tasks that need to be completed and documented in plans, procedures, or laboratory notebooks so that:

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- A. A hypothesis is defined and tested in a planned way with a statement of qualification conditions
- B. Variability and uncertainty conditions are identified and accounted for in experimental results
- C. Results are validated through a *peer review* (see def.) process and/or validation by the research community as evidenced by follow-on work by others, publication in high impact journals, citations, unsolicited invitations to present research results at national/international conferences and other forms of recognition.
- D. Qualified personnel in the field can reproduce the same results.

2.2 Applied Research

Applied research (see def.) is a process initiated with the intent of solving a specific problem or meeting a practical need. The initial process may involve basic research in selecting the best approach in accomplishing the applied research. Applied research is a proof of principle with its more explicit objectives, and warrants a set of milestones. Successful results may be applied to a future developmental activity. Applied research has a number of specific tasks that need to be completed and documented in plans, procedures, or laboratory notebooks so that:

- A. Proven theory is defined and tested in a planned way with a statement of qualification conditions
- B. A records management system maintains necessary information so that it is retrievable. Use of the laboratory notebook is the minimum acceptable method of records management to allow for data retrievability
- C. Data may be obtained, retained, and validated to ensure reproducibility of results.

2.3 Developmental Work

Developmental work (see def.) entails applying a proven theory and experimental results and their extension to its end use, e.g., use in a design environment. Basic and applied research may be a direct input to developmental work. Developmental work has a number of specific tasks that need to be completed and documented in plans, procedures, or laboratory notebooks so that:

- A. Developmental work documented in a structured format whether in a plan, procedure, or laboratory notebook.
- B. The plan is documented to lead to a more structured process management.

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- C. Tests are documented to show project success. Developmental tests will be defined. This includes performance boundaries. Qualification tests confirm predicted performance. Tests with or without *acceptance criteria* (see def.) are prescribed with requirements commensurate with the complexity and scale of the effort, and with the associated *risk* (see def.) to the public and workers, to the environment, and to the success of the project.

2.4 Multiple Research Type Work

A research project may involve multiple research types, (basic, applied and developmental). The *Principal Investigator (PI; see def.)* must identify and document when the research makes a transition between types of research. Requirements associated with each research type also change during this transition. The PI must document how the project will transition from one set of requirements to another during the change in research types. The PI must identify and document the transition process between development work on an engineered item and the design or production of the engineered item. The activities and controls to be placed on the development process activities will need to be defined so that the development work will support the design and production of the item.

3. RESPONSIBILITIES**3.1 Quality Assurance Organization**

- 3.1.1** The quality assurance organization is responsible for providing central direction and assessment of the company R&D quality assurance program, which includes, but is not limited to:
- A. Defining and disseminating requirements for R&D quality assurance, and assuring processes are implemented to satisfy those requirements
 - B. Ensuring that the R&D quality assurance program complies with applicable source requirements documents
 - C. Preparing, implementing, and maintaining this PRD
 - D. Ensuring the development, coordination, and maintenance of company implementing *procedures* (see def.) that establish *processes* (see def.) and responsibilities for implementing the R&D quality assurance program
 - E. Resolving and mediating the conditions with line management that are not compliant with R&D QA requirements to ensure conditions are corrected in an appropriate and timely manner

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- F. Providing *guidance* (see def.), coordination, and assistance to facilities in establishing and implementing R&D quality assurance program requirements
- G. Providing qualified quality engineers to support the line organization's implementation and maintenance of the R&D quality assurance program
- H. Conducting *surveillance* (see def.) of line organizations to *verify* (see def.) implementation of the quality assurance program.

3.1.2 Calibration Services Organization

The calibration organization is responsible for ensuring R&D metrology items and services used for *calibration* (see def.) activities comply with applicable quality requirements.

3.1.3 Procurement Quality Organization

The procurement quality organization is responsible for establishing and maintaining a centralized QA functional organization and being the single point of contact for all matters associated with the procurement process and *supplier* (see def.) quality. The procurement quality organization is responsible for integrating the R&D QA PRD with the company-wide procurement process. Other responsibilities include:

- A. Ensuring R&D procurement activities comply with R&D quality assurance requirements specified in this document
- B. Maintaining supplier qualification/*certification* (see def.), quality engineering, and product *verification* (see def.) services as required by established procedures
- C. Ensuring that procured R&D *items* (see def.) and *services* (see def.) comply with the requirements specified in *procurement documents* (see def.).

3.1.4 Cognizant Quality Engineer

The *Cognizant Quality Engineer* (see def.) is responsible for providing QA support, which includes, but is not limited to:

- A. Reviewing QA implementing procedures and selected program documents and operating procedures prepared within the performing organization for quality related activities.
- B. Assisting the line organization in identifying and resolving quality issues

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- C. Assisting in the preparation of internal implementing procedures
- D. Assisting the line organization in identifying and solving problems
- E. Reviewing and approving quality procurement documents
- F. Reviewing *nonconformance* (see def.) documentation during R&D support activities
- G. Performing and documenting independent QA inspections and tests where applicable
- H. Supporting evaluation of selected QA data, and reporting results to appropriate levels of management
- I. Supporting identifying and documenting necessary *witness* and *hold points* (see def.) through inspection planning and/or procedure review
- J. Providing analytical support for production processes as related to the QA discipline
- K. Performing surveillance activities to ensure compliance with QA program requirements
- L. Issuing *stop work orders* (see def.) when *conditions adverse to quality* (see def.) require immediate corrective action
- M. Assessing the supported organization's QA program and identifying management problems that hinder the organization from achieving its objectives.

3.1.5 Line Organizations

Line Organizations (see def.) are responsible for:

- A. Designating individuals or organizations responsible for implementing the requirements of the QA PRDs (e.g., *technical support organization* [see def.]) and defining the interfaces with *external organizations* [see def.]
- B. Identifying the responsibilities and authorities of those organizations and management
- C. Ensuring implementation of the QA program within their organizations
- D. Resolving quality deficiencies and implementing timely *corrective action* (see def.).

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3.1.6 Information Technology

The information technologies organization is responsible for providing central leadership and direction of the company software quality assurance program, which includes, but is not limited to:

- A. Ensuring R&D software development and modification activities comply with R&D quality assurance requirements specified in this document.
- B. Ensuring that R&D software and software *services* (see def.) comply with the requirements specified in this document.

4. REQUIREMENTS**4.1 Companywide Applications**

The requirements identified in this subsection (4.1) apply to the entire company for R&D activities unless exempted by INT-17, QA PRD Introduction, Subsection 2. A table in Appendix B presents the requirements that are applicable to each type of research.

4.1.1 Basic

- 4.1.1.1 An organizational structure shall be defined for R&D work to describe roles, responsibilities, and authorities that support achievement of work objectives. Interface responsibilities shall be defined between R&D and support functional elements.
 - 4.1.1.1.1 An authoritative relationship shall be defined for basic research. The PI and cognizant line management shall identify the individuals whose collaboration and peer/research community review activities document the credibility of the research process.
 - 4.1.1.1.2 The relationship of those performing specific tasks in applied research shall be defined to ensure task objectives are met individually or collectively.
 - 4.1.1.1.3 Roles, responsibilities, and authorities shall be defined for development and *support activities* (see def.). The definitions will address those doing the work and those who perform independent verification that work objectives have been met.

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Interface responsibilities with design and engineering functions shall be defined, as appropriate, to ensure that developmental results are useable.

4.1.1.2 The R&D quality assurance program is based on proven processes that govern the performance of successful scientific research. Qualified personnel engaged in selected investigation activities, careful reviews by independent competent peers, and documented results that are verifiable and able to withstand scrutiny by reviewers, potential users, and the research community.

4.1.1.2.1 For basic research, laboratory notebooks of investigators and other collected data assume great importance as evidence of what was done and the methods that were employed. The ultimate judgment of the quality of a basic research effort is rendered through peer reviews and/or research community acceptance.

4.1.1.2.2 Applied research shall be accompanied by more documentation than basic research; research plans, laboratory notebooks, testing, record keeping, and periodic reports commensurate with the scope of a given project.

4.1.1.2.3 For development activities, the plan that governs a developmental activity leads to a structured management of the entire process. The preparation and revision of design and process documentation, including milestones is formally documented. Tests are prescribed with requirements commensurate with the complexity and scale of the work, and with the associated risk to the public, workers, and environment, and the future success of the project.

4.1.1.2.4 Research and development activities completed for non-INEEL participants, such as work for others, may follow step 4.1.1.2.1 through 4.1.1.2.3, or the activities may be completed using documented requirements from the customer. Documented customer requirements must include as a minimum (when applicable): product documentation, data accuracy, type of peer review, fabrication standards, special processes, and inspection requirements.

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- 4.1.1.2.5 Often times a research customer specifies using a QA standard different than the standard used by the INEEL. In a case where the customer specifies a different QA standard, document the deviation.
- 4.1.1.3 Engineering design definition, verification and change control in all phases of R&D is applied using a graded approach.
- 4.1.1.4 Design control does not apply to design of experiments or experimental plans for basic and applied research; design of experiments and experimental plans shall be addressed as described in section 4.1.1.2.
 - 4.1.1.4.1 Design control does not apply to basic research.
 - 4.1.1.4.2 As research matures through the applied research phase, design control, commensurate with that activity (using graded approach) is used to support subsequent development work.
 - 4.1.1.4.3 For development and support activities, design control shall be implemented to meet the design requirements and ensure importance is placed on R&D results. This demonstrates the acceptability of an innovative design.
- 4.1.1.5 Procurement document control shall be applied to R&D activities. The approach shall anticipate the needs of the next phase of the R&D life cycle.
 - 4.1.1.5.1 The graded application of procurement document control for basic research shall be consistent with the maturity of the research.

For example, if final results of the work are expected in the next stage, and if the pedigree of materials being used could influence the usefulness of the results of the work during applied research, procurement document specifications will be controlled appropriately.
 - 4.1.1.5.2 As the applied research matures toward an expected completion point, procurement document control shall be applied to support the anticipated needs for future development work.

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- 4.1.1.5.3 For development and support activities, the level of procurement document control shall be applied to support a commercial design basis, i.e., engineering design criteria.
- 4.1.1.6 Research and development activities are planned to the extent possible. R&D work does not always lend itself to preplanned instructions and procedures; however, sufficient documentation will be developed to ensure replication of the work. The researcher/developer will document work methods and results in a complete and accurate manner.
- 4.1.1.6.1 When appropriate, basic research shall be documented in proposals, conceptual drawings, sketches, and laboratory notebooks. The level of detail shall be sufficient to withstand a successful peer review. Protocols on generating and safeguarding data and process development from basic research shall be developed if needed.
- 4.1.1.6.2 A work proposal for applied research shall describe the methods for researching the objectives of the applied research. As work progresses, the researcher shall document the work in instructions, laboratory notebooks, procedures, and drawings. These instructions, procedures, laboratory notebooks, and drawings will serve as guidance for subsequent development work.
- 4.1.1.6.3 Development and support activities shall be performed according to documented instructions, procedures, or drawings, as directed by the researcher/developer.
- 4.1.1.7 Document control is applied to R&D activities. As a minimum, laboratory notebooks shall be subject to document control procedures. Also, the process for developing intellectual property documentation is subject to document control.
- 4.1.1.8 R&D control of purchased materials, items, and services is required for all R&D activities. The degree of application shall support the desired results of the work, within specified performance boundaries. The need to ensure conformance with the specified requirements depends on the objectives of the work. If the quality of work results depends on the pedigree of the materials, items, or

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services, the work shall be planned to control purchased materials, items, or services.

4.1.1.9 R&D activities shall ensure identification and control of items. The degree of application shall support the desired results of the work within specified performance boundaries. If the quality of work results depends on the pedigree of the materials, items, or services, the work shall be planned to identify and control items.

4.1.1.10 The control of *special processes* (see def.) for R&D activities varies considerably as one advances from basic research through development.

4.1.1.10.1 In basic research activities, control of special process activities is left to the researcher to define. Process control is normally recorded in the laboratory notebook.

4.1.1.10.2 During applied research, special process control is minimal and is largely contingent upon the complexity of the research and the ability to duplicate the research if data were lost. Special process control instructions may be defined in the laboratory notebooks or operating logs.

4.1.1.10.3 Special process control for development and support activities is formalized. Formalization occurs at the project or program level. Work processes and supporting activities are defined, and work and operating procedures are developed and implemented with respect to safety considerations, quality, cost, schedule, and programmatic mission. Methods of implementation and training requirements are formally defined.

4.1.1.11 *Inspection* (see def.) processes for basic and applied research activities are minimal. Consideration may be given to performing inspection-like activities to establish process or product control limits.

4.1.1.11.1 Inspection activities do not apply to basic research because inspections require predetermined acceptance criteria.

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- 4.1.1.11.2 Inspection activities do not apply to applied research because inspections require predetermined acceptance criteria.
- 4.1.1.11.3 The researcher/developer will anticipate the need and plan for inspection criteria for advanced development work to interface with design process needs.
- 4.1.1.12 *Test* (see def.) control does not apply uniformly to basic and applied research. Where applicable, test methods and characteristics will be documented and the approaches and procedures recorded.
 - 4.1.1.12.1 Test control does not apply to basic research activities in which hypotheses are being evaluated. Test methods are not well defined and are usually determined by the researcher as the work progresses.
 - 4.1.1.12.2 In applied research test control will be specified to the degree that scientific knowledge is understood. These test procedures will serve as guidance for subsequent development work.
 - 4.1.1.12.3 Characteristics to be tested and test methods shall be specified for development and support work. The test results shall be documented and their conformance to acceptance criteria evaluated. Tests shall be planned, executed, documented, and evaluated.
- 4.1.1.13 The researcher shall specify the requirements of accuracy, precision, and repeatability of measuring and test equipment (M&TE) in a graded manner.
 - 4.1.1.13.1 In basic research, calibration might not be necessary during the initial (or scope-setting) stages of an activity.
 - 4.1.1.13.2 Depending upon the need for accuracy, precision, and repeatability of M&TE used in research, standard M&TE procedures will be followed. Where standard M&TE procedures are not used, effects of the instrument's performance on the uncertainty of the measurements and tests will be considered in the research.

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- 4.1.1.13.3 During the process development stage and for all R&D support activities, M&TE shall be controlled. The degree of control shall be dependent on the application of the measurement.
- 4.1.1.14 Handling, storage, and shipping controls are applied to R&D activities. Good laboratory practices may be defined as instructions for handling, storage, and shipping.
- 4.1.1.15 Inspection, test, and operating status have limited application for R&D activities.
 - 4.1.1.15.1 Inspection, test, and operating status of equipment or systems that support basic research are controlled at the discretion of the researcher.
 - 4.1.1.15.2 Inspection, test, and operating status of equipment and systems that have inspection and test requirements specified by the researcher will be identified by tags, markings, inspection and test records, or other suitable means for applied research.
 - 4.1.1.15.3 Tags, markings, inspection and test records, or other suitable means for development and support activities shall identify the status of items and processes for which inspections and tests are specified. The authority for application and removal of inspection and test identification shall be specified.
- 4.1.1.16 Control of nonconforming items applies to support activities only. The results of R&D activities are not expected to meet predetermined requirements; therefore, obtaining unexpected results does not constitute a nonconforming condition. The point at which a nonconformance can be identified is the point at which development work transitions into design or production of engineered items.
- 4.1.1.17 Corrective actions for conditions adverse to quality can be identified for R&D activities, depending on the certainty of operating assumptions and expected results. The documentation, reporting, and tracking of conditions adverse to quality are done at the discretion of the researcher.
 - 4.1.1.17.1 For basic research, using formal corrective action identification and tracking system is defined by the

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researcher(s), depending on the need to transmit information to peers.

4.1.1.17.2 For applied research, using formal corrective action identification and tracking system is defined by the researcher(s), depending on the need to transmit information to peers.

4.1.1.17.3 For development and support, responsibility shall be defined for the identification, cause, and corrective actions for significant conditions adverse to quality; these shall be documented and reported to appropriate levels of management. Follow-up actions shall be taken to verify implementation and effectiveness of corrective actions.

4.1.1.18 R&D activities produce *quality assurance records* (see def.). In many cases, the laboratory notebook or journal of the researcher is the QA record. Controls are needed for these documents, e.g., maintain copies of critical pages or access-controlled filing when not in use to preserve process repeatability and the QA record. Electronic media may be used to record data and shall be subject to appropriate administrative controls for handling and storage of data.

4.1.1.19 *Audits* (see def.) are performed in a graded manner. R&D audit activities include normally accepted assessment practices, peer reviews, or both.

4.1.1.19.1 For basic research, the objectives of the audit process may be achieved by line management assessments or as part of the peer review activities, if the peer review process is sufficiently comprehensive.

4.1.1.19.2 As knowledge gained by basic research matures through applied research, audits will be used in conjunction with peer reviews to support subsequent development work.

4.1.1.19.3 For development and support, audits responsibility shall be defined and the results of these audits shall be documented and reported to appropriate levels of management. Follow-up actions shall be taken to verify implementation and effectiveness of corrective actions.

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4.1.1.20 The R&D *software* (see def.) quality assurance program is based on proven processes that govern the performance of successful scientific research.

4.1.1.20.1 Software used to support basic research shall be documented in laboratory notebooks or other project files where appropriate. This information and other collected data assume importance as evidence of what was done and the methods that were employed. The software documentation and other information are reviewed through peer reviews and research community acceptance.

4.1.1.20.2 Applied research software will be accompanied by more documentation than basic research; software development plans, laboratory notebooks, testing, acceptance testing, record keeping, configuration management, and periodic reports commensurate with the scope of a given project.

4.1.1.20.3 For software developed during development activities, the plan that governs a developmental activity leads to a structured management of the entire process. The preparation and revision of software design and process documentation, including milestones shall be documented. Tests with requirements commensurate with the complexity and scale of the software, and with the associated risk to the public, workers, and environment, and the future success of the project shall be documented.

4.1.1.20.4 Research and developmental activities completed for non-INEEL participants such as work for others, may follow the above step 4.1.1.2.1 through 4.1.1.2.3, or the activities may be complete using documented quality requirements from a customer.

4.1.1.20.5 Documented customer requirements must include as a minimum (when applicable): technical and functional requirements for the software, testing, and documentation requirements.

4.1.1.20.6 Often times a research customer specifies using a QA standard different than the standard used for the

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INEEL. In a case where the customer specifies a different QA standard, document the deviation.

4.1.2 Applying Controls

- 4.1.2.1 QA controls (grading) shall be applied to the degree commensurate with the:
- A. The type of research being performed.
 - B. Function or end use of the item.
 - C. Consequence of failure (risk) of the item.
 - D. Importance of the data being collected or analyzed.
 - E. Complexity of design or fabrication of the item or design or implementation of the activity.
 - F. Reliability of the process.
 - G. Reproducibility of the results.
 - H. Uniqueness of the item or degree of standardization.
 - I. History of the item or service quality.
 - J. Necessity of special controls or processes.
 - K. Degree to which functional compliance can be demonstrated through inspection or test.
 - L. The relative importance to safety, safeguards and security; the magnitude of any hazard involved.

4.1.3 Planning Work

- 4.1.3.1 Planning shall be documented to ensure work is accomplished under suitably controlled conditions.
- 4.1.3.2 Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied.
- 4.1.3.3 Planning shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items, and for verification of that quality.

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4.1.4 Personnel Qualification

NOTE: *The Principal Investigator addresses personnel training and qualification requirements. As a minimum, personnel shall be sufficiently proficient in the activities to ensure that the activity supports the research mission and provides accurate results.*

4.1.5 QA Program Information Management

4.1.5.1 Relevant organization management shall, on a continuing basis, be apprised of the status, adequacy, and compliance aspects of the QA program.

4.1.5.2 Appropriate management shall receive, as a minimum, audit reports, surveillance reports, trending reports, and *management assessment* (see def.) reports.

4.1.6 Records

4.1.6.1 All records generated by this document that are designated in implementing documents as quality assurance records shall be controlled in accordance with PRD-5088, 17.1 Quality Assurance Records.

5. DEFINITIONS

NOTE: *Sources of definitions are identified after each entry as follows: [1] Company Definition; [2] NQA-1-2000; [3] DOE/RW-0333P; [4] ANSI/NCSL Z540-1-1994; [5] 10 CFR 830. Information from sources other than the above are identified by title.*

Refer to LST-199, Definitions, in the QA Manual for any definitions that are not listed here.

acceptance criteria. Specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents. [2]

applied research. A process, the objective of which is to gain knowledge or understanding necessary for determining the means by which a recognized and specific need may be met. [2]

audit. A planned and documented activity performed to determine by investigation, examination, or evaluation of object evidence, the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or

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inspection activities performed for the sole purpose of process control or product acceptance. [2]

basic research. A process, the objective of which is to gain a fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward processes or products in mind. [2]

calibration. The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system and the corresponding standard or known values derived from the standard. [4]

certification. The act of determining, verifying, and attesting in writing to the achievement or compliance with specified requirements. [3]

cognizant quality engineer. A person that has responsibility for providing QA support to a division, department, program/project or other line organizational unit. [1]

condition adverse to quality. An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and non-conformances. A state of noncompliance with quality assurance program requirements. A significant condition adverse to quality is one if uncorrected, could have a serious effect on safety or operability. [1]

corrective action. Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition. [2], [3]

development. Systematic use of the knowledge or understanding gained from research, directed toward the creation of useful materials, devices, systems, or methods, including prototypes and processes.

developmental work. Use of existing scientific or technical knowledge directed toward:

- Bringing a solution to bear on a specific problem by generating the technical, cost, and engineering data required for demonstration.
 - Producing new or substantially improved materials, products, devices, or services.
 - Installing new processes, system and services.
 - Improving substantially those processes, systems, and services already installed.
- [2]

external organization(s). Companies, special interest groups, state agencies, DOE counterparts or other work groups that are outside the company's organization structure or influence. [1]

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graded approach. The process by which the extent (level of rigor) of application of controls and verification efforts is determined on the basis of importance and significance of activities, and associated consequences of the activities. [2]

guidance. A suggested practice that is not mandatory in programs intended to comply with this Standard. The word “should” denotes guidance; the word “shall” denotes a requirement. [2]

hold point. Hold points are procedure steps at which the user must wait for another person to do something or for some other event to occur. Hold points are designated by using a descriptive phrase, such as RADIOLOGICAL HOLD, that indicates the type of hold involved. [1]

inspection. An examination or measurement to verify whether an item or activity conforms to specified requirements. [2]

item. An inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or support system. [2]

laboratory notebook. A notebook maintained by a researcher that documents the methodology and processes followed during research. [1]

line organization. Any organization that is responsible for conducting work. [1], [DOE G 450.4-1]

management assessment. (1) A quality assurance program verification that is conducted by management above or outside the Quality Assurance organization and that evaluates the scope, status, adequacy, programmatic compliance, and implementation effectiveness of the quality assurance program. [3] (2) An evaluation by line management of work, processes, and activities for which they have assigned responsibility. [1]

nonconformance. A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate. [1]

peer review. A critical review of research and development work that is performed by one or more individuals who collectively have scientific expertise at least the equivalent of those who performed the work. [2]

Principal Investigator (PI). Person assigned to complete or supervise the completion of a research task. This individual may have the company title of a Principal Investigator, Project Manager, Program Manager, etc. [1]

project execution plan (PEP). A document generated to describe the processes and steps to perform a program or project. A PEP is used to identify unique customer requirements applicable to a particular program or project (includes QA requirements) and provides an index or a description of the procedures that implement program requirements. [1]

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procedure. A document that specifies or describes how an activity is to be performed. [2]

process. A series of actions that achieves an end result or accomplishes work. [3]

procurement document. Purchase orders, contracts, specifications, or other documents used to define technical and quality assurance requirements for the procurement of items or services. [3]

project file. A file that contains project documentation. This documentation includes but is not limited to : project description, communication with customers, project milestones, test results, a list of personnel working on the project, special condition required to obtain desired results and equipment calibration. While the project is active, this documentation may be in various locations as necessary to support project needs. A project file will be indexed and stored as necessary to support document retrievability.

quality assurance (QA). The planned and systematic actions necessary to provide adequate confidence that an item will perform satisfactorily in service. [2]

quality assurance record. A completed document (or other medium) that furnishes evidence that items or work complies with requirements. [3]

quality program plan (QPP). A document generated when there is a need for a program or project to depart from the quality assurance program and its implementing procedures. A QPP is used to identify unique customer quality assurance requirements applicable to a particular program or project and provides an index or a description of the procedures that implement program requirements. [1]

R&D. Research and development work undertaken to acquire new knowledge (includes data) or to improve existing knowledge and the determination of the application of this knowledge to devise new applications or solutions to problems. The basic criterion in distinguishing R&D activities from non-R&D activities is the presence (in R&D activities) of scientific and/or technological uncertainty and the resolution of that scientific and/or technological uncertainty. R&D encompasses the following categories: applied research, basic research, demonstration/deployment, and development. [2]

Risk. A quantitative or qualitative measure of the likelihood and unfavorable consequence of an action. Consequences may be related to the public or employee safety, the environment, programmatic impact, cost, schedule, or public perception. [2]

service. The performance of activities such as design, construction, fabrication, inspection, environmental remediation, waste management, laboratory sample analysis, nondestructive examination/testing, environmental qualification, equipment qualification, repair or installation, or the like. [2], [3], [DOE 0 414.1A]

software. Computer programs, procedures, rules, and associated documentation and data pertaining to the operation of a computer system. [1]

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special process. A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product. [3]

stop work order. A formal directive issued by management that work must be stopped until resolution of the related significant condition averse to quality. [3]

supplier. Any individual or organization who furnishes items or services in accordance with a procurement document. All-inclusive term used in place of the following: vendor, seller, contractor, subcontractor, dealer, fabricator, consultant, manufacturer, distributor, and their subtler levels. [1]

support activities. Secondary actions associated with R&D work that are conventional in nature and allow the primary purpose of work to be accomplished. [2]

surveillance. The act of observing real-time activities and/or reviewing documentation to verify conformance with specified requirements and to evaluate their adequacy and effectiveness. [3]

technical support organization. The group that is responsible for providing technical support to the design organization for disciplines such as inspection, criticality analysis, industrial safety, radiation protection, environmental engineering, or computer programming. [1]

test/testing. An element of verification for determination of the capability of an item to meet specified requirements by subjecting the item to a set of chemical, physical, environmental, or operating conditions. [2], [3]

verification. The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements. [3]

verify. The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining whether items, processes, services, or documents conform to specified requirements. For deficiency reports, the act of verifying is performed by an individual who is independent of the deficiency corrective actions. [1]

witness point. Witness points are procedure steps at which the user must wait for another person to independently observe as the user performs work to procedure, specification, drawings or other forms of criteria. [1]

6. REFERENCES

ASME NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications

7. APPENDICES

Appendix A, Research and Development Requirements Matrix

Appendix B, 25.1 Basis

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APPENDIX A

Research and Development Requirements Matrix

Program Requirement Document	Research and Development Activities			Research and Development Support Activities
	Basic	Applied	Development Work	
PRD-5070, Organization	A	A	A	A
PRD-5070, Quality Assurance Program	A	A	A	A
PRD-5074, Design Control	NA	GA	A	A
PRD-5075, Procurement Document Control	A	A	A	A
PRD-5076, Instructions, Procedures, and Drawings	GA	GA	GA	A
PRD-5077, Document Control	A	A	A	A
PRD-5078, Control of Purchased Items and Services	A	A	A	A
PRD-5079, Identification and Control of Items	A	A	A	A
PRD-5080, Control of Special Processes	GA	GA	A	A
PRD-5081, Inspection	NA	NA	GA	A
PRD-5082, Test Control	NA	GA	A	A
PRD-5083, Control of Measuring and Test Equipment	GA	GA	A	A
PRD-5084, Handling, Storage, and Shipping	A	A	A	A
PRD-5085, Inspection, Test, and Operating Status	GA	GA	A	A
PRD-5086, Control of Nonconforming Items	NA	NA	NA	A
PRD-5087, Corrective Action	GA	GA	A	A
PRD-5088, Quality Assurance Records	A	A	A	A
PRD-5089, Quality Assurance Internal and External Audits	GA	GA	A	A
PRD-5092, Software Quality Assurance	NA	GA	A	A
Notes: “A” indicates that the requirement is applicable “GA” indicates graded applicability with an explanation in the controlling documents “NA” indicates not applicable for the R&D activity				

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25.1 Basis

Source	Citation	Requirement	Comments
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2, Guidance on Graded Application of Quality Assurance (QA) for Nuclear-Related Research and Development	601.1	4.1.1.1	Consensus Standard (CS)
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	601.2	4.1.1.1.1	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	601.3	4.1.1.1.2	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	601.4	4.1.1.1.3	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	602.1	4.1.1.2	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	602.2	4.1.1.2.1	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	602.3	4.1.1.2.2	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	602.4	4.1.1.2.3	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	602.1	4.1.1.2.4	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	602.1	4.1.1.2.5	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	603.1	4.1.1.3	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	603.1	4.1.1.4	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	603.2	4.1.1.4.1	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	603.3	4.1.1.4.2	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	603.4	4.1.1.4.3	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	604.1	4.1.1.5	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	604.2	4.1.1.5.1	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	604.3	4.1.1.5.2	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	604.4	4.1.1.5.3	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	605	4.1.1.6	CS

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Source	Citation	Requirement	Comments
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	605.1	4.1.1.6.1	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	605.2	4.1.1.6.2	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	605.3	4.1.1.6.3	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	606	4.1.1.7	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	607	4.1.1.8	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	608	4.1.1.9	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	609.1	4.1.1.10	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	609.2	4.1.1.10.1	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	609.3	4.1.1.10.2	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	609.4	4.1.1.10.3	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	610.1	4.1.1.11	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	610.2	4.1.1.11.1	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	610.3	4.1.1.11.2	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	610.4	4.1.1.11.3	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	611.1	4.1.1.12	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	611.2	4.1.1.12.1	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	611.3	4.1.1.12.2	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.	611.4	4.1.1.12.3	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	612	4.1.1.13	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	612.1	4.1.1.13.1	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	612.2	4.1.1.13.2	CS

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Source	Citation	Requirement	Comments
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	612.3	4.1.1.13.3	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	613	4.1.1.14	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	614.1	4.1.1.15	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	614.2	4.1.1.15.1	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	614.3	4.1.1.15.2	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	614.4	4.1.1.15.3	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	615	4.1.1.16	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	616.1	4.1.1.17	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	616.2	4.1.1.17.1	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	616.3	4.1.1.17.2	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	616.4	4.1.1.17.3	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	617.1	4.1.1.18	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	618.1	4.1.1.19	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	618.2	4.1.1.19.1	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	618.3	4.1.1.19.2	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	618.4	4.1.1.19.3	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	603.1	4.1.1.20	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	603.1	4.1.1.20.1	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	603.1	4.1.1.20.2	CS
NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 4.2	603.1	4.1.1.20.3	CS